UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,953	06/12/2006	Tomas Fabo	1501-1317	9965

466 7590 05/17/2010

YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
05/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/553,953
Filing Date: June 12, 2006
Appellant(s): FABO, TOMAS

Robert A. Madsen
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed Feb. 16, 2010 appealing from the Office action mailed May 19, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after the previous non-final rejection contained in the brief is correct. No amendments have been made after the Final Rejection mailed May. 19, 2009.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION." No rejections are withdrawn herein and no new grounds of rejection are presented herein.

(7) Claims Appendix

The copy of appealed claims 9-16, 19, and 20 that appears on pages 13-17 of the Appendix to the appellant's brief is correct.

(8) Evidence Relied Upon

6,471,985	GUYURON	10-2002
4,925,671	ABBER	5-1990

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 9, 10, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUYURON (U.S. 6,471,985; Issued Oct. 29, 2002).

1. Guyuron discloses a method of treating a skin wound involving covering the wound with a room temperature vulcanizing (RTV) silicone composition comprising a crosslinkable polymer, and permitting the composition to cure to form a protective membrane (abstract; col. 2, lines 55-59). Guyuron teaches that the silicone composition is applied over the wound (col. 1, lines 7-9 and 54-56). Since an object of Guyuron's invention is to prevent infection of the wound (col. 1, lines 19-23 and 62-63; col. 2, lines 49 and 58), an ordinary artisan would understand Guyuron's teachings to mean that the silicone composition is applied over a wound, including the surrounding non-wounded skin as is typical of methods aiming to prevent infection by sealing a wound in order to prevent the entrance of bacteria or other contaminants. Guyuron teaches a method of applying the silicone composition (col. 1, lines 54-56; claims 1 and 21) by mixing a two-

part composition, wherein both parts have a viscosity between 5 and 300 Pa•s (e.g. where the first part has a viscosity of about 60,000 to about 120,000 cps (equivalent to 60-120 Pa•s) while the second part has a viscosity from about 40,000 cps to about 100,000 cps (equivalent to 40-100 Pa•s)) (col. 10, lines 20-25). Guyuron further teaches that suitable polysiloxanes for the invention range in viscosity from about 0.01 Pa•s to 2500 Pa•s (col. 3, lines 19-26). It is noted that the preferred Formula I taught by Guyuron is a vinyl-substituted polydimethylsiloxane (col. 3, lines 30-65, particularly lines 64-65; claim 3), which is the same compound preferred in the instant application (par. [0019]). Thus, the preparation comprises a composition that is "highly viscous" according to the definition set forth in par. [0017] of the instant specification.

2. Furthermore, Guyuron teaches that the composition cures by means of crosslinking after application (col. 2, lines 1-9). The cured composition is a skin-friendly elastomer (claims 2 and 22) and adheres to the skin (col. 1, lines 59 and 60). Guyuron does not explicitly disclose the softness of the compositions in terms of the measurements defined in pars. [0041] and [0068] of the instant application. However, Guyuron teaches the amount of the crosslinkable polysiloxane component varies depending on the desired physical properties of the RTV silicone composition (such as the desired uncured viscosity and cured hardness) (col. 4, lines 41-44). Additionally, Guyuron teaches that suitable wound dressings must stretch/flex to accommodate skin or bodily movement and that the compositions of the invention are flexible when cured (col. 1, lines 27-28; col. 10, lines 48-49). It is well within the purview of the ordinary artisan to adjust the amount of the crosslinkable polysiloxane component, as taught by

Guyuron depending on the desired physical properties of the composition, both cured and uncured. Since Guyuron teaches that the uncured composition has a viscosity that meets the limitations of being "highly viscous" according to the instant specification, and teaches a final cured preparation that is flexible to skin and body movements, it is likely that the compositions of Guyuron meet this limitation as well. However, in the absence of an explicit teaching of the softness of the composition, it would have been *prima facie* obvious to the ordinary artisan to optimize the softness by adjusting the amount of crosslinkable polysiloxane and other components as taught by Guyuron. One would have been motivated to produce a final cured elastomeric preparation that is flexible since Guyuron teaches that such a property is necessary in these types of wound dressings, and such a composition would meet the limitation of "soft" according to the instant specification. Thus, the teachings of Guyuron render claim 9 obvious. Guyuron teaches applying the preparation in a thickness from about 0.1 mm to about 5 mm (abstract; col. 2, lines 7-8; claim 1), rendering claim 10 obvious.

3. Regarding claim 14, Guyuron teaches applying silicone composition by covering the wound to form a protective membrane (abstract; col. 2, lines 55-59; claim 1). Guyuron teaches that the silicone composition is applied over the wound (col. 1, lines 7-9 and 54-56). An ordinary artisan would understand Guyuron's teachings to mean that the silicone composition is applied over a wound, including the surrounding non-wounded skin as is typical of methods aiming to prevent infection by sealing a wound in order to prevent the entrance of bacteria or other contaminants. Moreover, it is well within the skill of an ordinary artisan to determine the precise amount and pattern of

application optimal for a particular wound depending on the shape and nature of the wound. Thus, it would be *prima facie* obvious to an ordinary artisan to apply Guyuron's preparation over a wound and around the outside edge of a wound in the range of 2-100 mm as is typical with other liquid bandages, ointments, and topical treatments known in the art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 9, 11-13, 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guyuron in view of ABBER (U.S. 4,925,671; Issued May 15, 1990).

4. Guyuron renders obvious the method of claims 9, 10, and 14, as discussed *supra*. Guyuron teaches that the silicone composition may be custom fit to any contoured or shaped surface. Guyuron also teaches that the compositions should be used in conjunction with a release agent when other objects are used to apply the

composition (col. 10, lines 41-46). Guyuron teaches that the composition is preferably adherent for about 30-45 minutes after mixing the components, but that full curing may not occur for several hours or days (col. 10, lines 34-58). Thus, the ordinary artisan would readily recognize that the composition of Guyuron would be adhesive for some time after application, and would adhere to a variety of surfaces. While clearly teaching that the composition is suitable as an adhesive, Guyuron does not teach the use of the composition as an adhesive for other medical articles *per se*.

5. However, use of similar silicone compositions for this exact purpose was well known in the art at the time of the invention. For example, Abber discloses pressure sensitive adhesives comprising silicones including crosslinked vinyl-substituted dimethyl siloxanes (col. 4, lines 37-43; col. 7, lines 35-39). It is noted that these compositions have viscosities of about 20 Pa•s (col. 4, lines 37-43) and are therefore "highly viscous" according to the instant specification. These compositions are intended for use as adhesives for various medical devices (abstract; col. 1, line 11-16; claims 1-4). Since Guyuron suggests that the composition can adhere to articles in addition to wounds and human skin, an ordinary artisan would readily have envisioned the use of the compositions taught by Guyuron as adhesives for a variety of medical devices as taught by Abber. Such a use amounts to combining known prior art elements (i.e. crosslinked silicone compositions) according to known methods (i.e. use of as these compositions as adhesives for medical devices) to yield predictable results (i.e. acceptable adhesion of the medical devices to the skin). The ordinary artisan would have had a high expectation of success in doing so since the prior art establishes that substantially

identical compositions are useful for exactly the same purpose and since Guyuron suggests such a use. Thus, the combined teachings of Guyuron and Abber render claims 11 and 19 obvious.

6. Regarding claim 12, Abber teaches the application of the adhesive to a medical device (col. 1, lines 35-37 and 45-47; col. 4, lines 17-22). Thus, it would have been *prima facie* obvious to an ordinary artisan to apply the preparation of Guyuron to the article before applying it to the skin (see the above discussion of claim 11). After doing so, placing the article to the skin would be applying the preparation to the skin at the same time as the article (i.e. applying them concurrently). Thus, the combined teachings of Guyuron and Abber render claim 12 obvious.

7. Regarding claims 13 and 20, it is noted that Guyuron teaches a composition that is substantially identical to that which is instantly claimed. Thus, it is the examiner's position that the composition of Guyuron is also "designed such that its adherence to the article for medical use is greater than its adherence to skin after curing." Indeed, such is suggested by Guyuron since a release agent is required when using the composition with articles other than skin (col. 10, lines 41-46), whereas the dressings of Guyuron possess releasability (e.g. they can be removed by gently peeling them off the skin) (col. 11, lines 50-53), enabling non-damaging removal from a wound (col. 1, lines 59-62). Furthermore, Abber teaches that the silicone adhesive of the invention are particularly suited to medical applications since it is easily removed from the skin, but has a high degree of adhesion over a prolonged period. Thus, even if, *in arguendo*, the composition taught by Guyuron did not meet this limitation (which it does), it would have

been *prima facie* obvious to design the composition to have these qualities per the teachings of Guyuron and Abber, rendering claims 13 and 20 obvious. Abber teaches that pressure-sensitive adhesives for use on human skin are used typically in bandages or other therapeutic devices which must adhere to the skin for a prescribed period of time and teach that the adhesive of the invention is useful for this purpose (col. 1, lines 18-21; col. 4, lines 64-66). Thus, it would have been *prima facie* obvious to an ordinary artisan to use the adhesive with a bandage (i.e. a wound dressing) or other medical device per the teachings of Abber, rendering claim 15 obvious.

8. Regarding claim 16, Abber teaches the use of the adhesive in conjunction with bandages such as transdermal therapeutic devices (abstract; col. 2, lines 63-68). Abber describes some types of transdermal devices used with the adhesive as having semi-permeable layers with respect to the drug in the transdermal device (col. 1, lines 48-50; col. 4, lines 60-64), but clearly states that the adhesives have general applicability to essentially any transdermal device which must be adhesively placed in contact with the skin (col. 5, lines 4-10). It is noted that the instant specification defines a liquid-tight dressing as merely having one layer that is liquid-tight (paragraph [0026]). Transdermal devices comprising at least one liquid-tight layer are well known in the art. An ordinary artisan would be motivated to use such a liquid-tight device in conjunction with the silicone adhesives taught by Guyuron because Guyuron teaches that the compositions act as barriers to retain moisture in the wound (col. 10, lines 63-65; col. 11, lines 16-18). Thus, to maintain such a moisture retentive property of a wound dressing, one would select a liquid-tight wound dressing for use with this adhesive, rendering claim 16

obvious. This is especially true with Guyuron, since Guyuron does not teach that the compositions are completely water impermeable.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

(10) Response to Argument

Appellant's arguments have been fully considered but are not persuasive. Appellant argues that claims 9 and 10 recite application to non-wounded skin. Appellant further cites portions of the specification relating to an undefined "risk" of the composition entering the wound (brief, pgs. 2-3).

First, it is noted that the instant **claims** do not exclude application of the silicone elastomer composition (hereinafter composition) from the wound itself, in contrast to what appellant *implies* the claims require. Second, the alleged "risk" is not even discussed in the specification. In fact the word "risk" only appears twice in the entire disclosure once on p. 16 and once on p. 20 of the specification In both occurrences, the

term "risk" is discussed in the context of the composition remaining at the site of application. There is no teaching that the composition should be excluded from the wounded tissue, nor is there mention of any reason why (e.g. toxicity, etc.) the composition cannot and should not contact the wound itself. Indeed since Guyuron uses the very same composition for application to wounds, it is clear that application of this composition to wounded tissue is acceptable. Application to wounded tissue, non-wounded tissue, or both is a mere design choice, and any of these limited possibilities would be immediately envisaged by the skilled artisan. Again, the claim language does *not* exclude the composition from contacting the wound itself, in addition to contacting some of the non-wounded skin around the wound as well. This interpretation is completely in line with appellant's specification. In response to appellant's argument that the references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., the exclusion of the composition from the wound) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant argues that there is no explicit teaching of applying the composition entering the wound (brief, pgs. 3-4). Appellant argues that there is no implicit teaching or suggestion of applying the composition to non-wounded skin (brief, pgs. 4-5), and argues that the rejection is based on an assumption by the examiner (brief, p. 3).

The instant rejections were made under U.S.C. 103, which does not require an *explicit* teaching. The MPEP states: "The rationale to modify or combine the prior art

does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli* Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning). See MPEP § 2144 (I).

It is true that Guyuron does not use the words "non-wounded skin", which are used in appellant's claims, but that is not the standard for obviousness. Guyuron uses the term "wound" throughout the patent. While it could be argued that the term "wound" inherently includes the skin immediately adjacent to the wound (and it is the examiner's position that it does), the relevant question in this case is what the term "wound" would convey to a skilled artisan. Taking Guyuron as a whole, the term "wound" clearly includes the intact, non-wounded skin surrounding the wound. In the prior Office Action, the examiner has presented a detailed rationale, based on sound logic, scientific reasoning, and Guyuron's direct teachings (see Facts 1 and 2 below) to support the

finding that a skilled artisan would be led to a method applying Guyuron's composition not just the wounded tissue itself (which is distinct from the general meaning of "wound" in the art), but the non-wounded skin surrounding the wound as well.

It is clear that Guyuron's composition would be applied to the non-wounded skin surrounding a wound as well as to the wound itself because:

Fact 1: Guyuron intends to prevent infection of the wound by blocking the entrance of bacteria or other contaminants (see Guyuron at col. 1, lines 19-23 and 62-63; col. 2, lines 49 and 58; col. 11, lines 18-20).

Guyuron teaches:

> "In another embodiment, the present invention provides a method of preventing infection of surgical wounds." (col. 2, lines 48-49; emphasis added)

> "The present invention involves using a room temperature vulcanizing (RTV) silicone composition to cover surgical wounds...to facilitate at least one of wound healing, infection prevention, and scarring minimization." (col. 2, lines 55-59; emphasis added)

If, as appellant argues, Guyuron's composition were applied *only* to wounded tissue, and no part of it touched non-wounded skin, there would, by definition, be at least some amount of wounded tissue left unprotected between the composition and the non-wounded skin. A skilled artisan would never apply Guyuron's compositions in this way, unless Guyuron himself explicitly stated that the composition could not be applied to the non-wounded skin, which Guyuron does *not* state. If, as appellant suggests, the artisan only applied the composition to wounded tissue, this configuration would allow for the entrance of bacteria and other contaminants between the non-wounded skin and the composition covering only the wounded tissue. Guyuron teaches that an *exposed* wound is an ideal breeding ground for harmful bacteria (col. 1, lines 20-21). Clearly,

Guyuron is directed to an invention that completely covers the entire wound so as to prevent exposure of any part of the wound. An artisan would know that the simplest, and most conventional, way to completely cover a wound is to apply the wound covering composition over the wound and, at least to some extent, also to the surrounding non-wounded tissue, thereby effectively sealing the wound. By appellant's argument, Guyuron's composition cannot contact the non-wounded skin (i.e. seal the wound). This is clearly contrary to the object of Guyuron's invention, as would be recognized by the ordinary artisan.

Fact 2: Guyuron teaches a continuous or substantially continuous membrane that is intended to retain moisture in the wound (col. 11, lines 15-18).

Guyuron teaches:

> "The thickness of the RTV silicone composition is sufficient to act as barrier to infection causing species as well as sufficient to retain moisture in the wound." (col. 10, lines 63-65; emphasis added)

> "The RTV silicone composition forms a membrane that is continuous or substantially continuous. The continuous nature of the membrane contributes to the ability of the membrane to retain moisture in the wound. The continuous nature of the membrane contributes to the ability of the membrane to act as a bacterial barrier." (col. 11, lines 15-20; emphasis added)

If, as appellant argues, Guyuron's composition were applied *only* to wounded tissue, and no part of it touched non-wounded skin, there would, by definition, be at least some amount of wounded tissue left unprotected between the composition and the non-wounded skin. This situation would also allow moisture to escape from the wound, for example around the uncovered edges of the wound that would (according to appellant) not be sealed by Guyuron's composition because it can allegedly not contact the non-wounded skin around the wound. This is clearly contrary to another object of

Guyuron's invention, moisture retention, as would be recognized by the ordinary artisan. Further, one of skill in the art would not recognize a protective composition, applied only to the wounded tissue, and not contacting the adjacent skin (as argued by appellant), to be continuous or substantially continuous as taught by Guyuron.

Appellant's assertion that there is no implicit teaching of application to non-wounded skin is incorrect. Clearly, an ordinary artisan would understand Guyuron's teachings to mean that the silicone composition is applied over a wound (*covering* the wound as directly taught by Guyuron), including the surrounding non-wounded skin as is typical of methods aiming to prevent infection by sealing a wound in order to prevent the entrance of bacteria or other contaminants and retain moisture to aid in healing. Thus, the alleged assumption that appellant attributes to the examiner was not an assumption, but is a logical result of reading Guyuron, is based on scientific reasoning, and is supported by Guyuron's own teachings.

Three further aspects of appellant's arguments from the bottom of p. 4 to the top of p. 5 of the brief are discussed since these arguments are unclear.

1) The first par. under item **b** on p. 4 of the brief states that support for one of the examiner's positions was col. 1, lines 59 and 60. However, this is incorrect. As stated (correctly) by appellant, this citation relates to adhesion of the composition, not the result of appellant's argument. The correct citations are found in the top par. of p. 8 of the Office Action dated 5/19/09, and the reasoning applied therein, which is further discussed above.

2) In the par. bridging pgs. 4-5 of the brief, appellant asserts that Guyuron's compositions are applied to the whole wound bed without having to apply the composition to the non-wounded skin surrounding the wound bed. Appellant provides no citation to support this assertion, and no such teaching could be located in Guyuron.

3) In the 1st full par. of p. 5, appellant asserts that:

> "Even if some composition unintentionally reached outside the wound bed, this contact would not teach the claimed method of applying a protective layer to non-wounded skin (stratum corneum), e.g., comprising applying a preparation which adheres to non-wounded skin, and allowing the preparation to cure to form an elastomer which adheres to the non-wounded skin, as recited in independent claim 9."

This is appellant's *opinion*, with which the examiner strenuously disagrees. Again, it is pointed out that the instant claims in no way exclude the composition from the wounded tissue, and do not limit application of the composition to ONLY the non-wounded skin. It is also pointed out that the ability of the composition to adhere to skin is an inherent property of the composition, which is identical to that taught by Guyuron. While unintentional application of Guyuron's composition to non-wounded skin would read on the claims, it is noted that what is suggested by Guyuron is not unintentional application. Rather, to any ordinary artisan, Guyuron suggests intentionally applying the composition over the entire wound, which based on Guyuron, an artisan would understand to include the non-wounded skin adjacent to the wound. This is so because, as discussed above, it is the most logical, reasonable way to achieve the objects of Guyuron's invention.

Appellant argues that Guyuron teaches away from the claimed method (brief, pgs. 5-6).

Guyuron does not teach away from the claimed invention. Appellant describes how an advantage of Guyuron's compositions is that they do not have to be cut and fit to a wound. It is unknown how this is relevant to the issue of the obviousness of applying Guyuron's compositions to the non-wounded skin surrounding a wound, and appellant does not make any connection to this issue. Appellant admits that:

> "GUYURON requires that the composition forms a membrane over the wound to retain moisture in the wound. See, e.g., Column ii, lines 15-18." (see p. 5, 2nd par. under item **c**)

This teaching by Guyuron, acknowledged by appellant, fully supports the obviousness of applying Guyuron's composition to the non-wounded skin adjacent to a wound (see Fact 2 above). Based on this teaching, it is unknown how an artisan would be discouraged from modifying Guyuron at all. Moreover, there is no "modification" suggested for Guyuron in order for Guyuron to read on the claims. As discussed above, an ordinary artisan reading Guyuron would practice Guyuron's method by applying the composition as a covering over a wound, applying the composition at least to some extent to the surrounding non-wounded tissue, thereby effectively sealing the wound. No modification is necessary, it is only an *explicit* teaching that is lacking. Practicing Guyuron's method (which renders the instant claims obvious), cannot, by definition, render Guyuron unsatisfactory for its intended purpose (see the last full par. of p. 5 of the brief). From appellant 's arguments on pgs. 5-6, it appears that appellant believes that the examiner has suggested that one reading Guyuron would not apply Guyuron's composition to a wound, but rather only around the periphery of a wound. That is not what has been suggested. Rather, practicing Guyuron's method renders the claims

obvious without the alleged modification. Modification is not required for the Guyuron to render the instantly claimed method obvious.

Appellant argues claim 14 is directed to applying the preparation around the wound, and presents arguments for claim 14 substantially similar to the arguments presented for claims 9 and 10 (brief, pgs. 6-9).

The arguments with respect to claims 9 and 10 are addressed *supra*, and that discussion is incorporated into the discussion of claim 14. In addition to those arguments, the response regarding claim 14 is summarized as follows: the instant claims in no way exclude the composition from the wounded tissue, and do not limit application of the composition to ONLY the non-wounded skin. Guyuron's method, applying the same composition to the wound *and* (implicitly) to the skin adjacent to the wound as well, renders the instantly claimed method obvious. It is the examiner's position that any artisan practicing Guyuron's method would surely apply the composition to the non-wounded skin around the wound within the wide width range 2-100 mm) instantly claimed. Furthermore, it is well within the skill of an ordinary artisan to determine the precise amount and pattern of application optimal for a particular wound depending on the shape and nature of the wound. Thus, it would be *prima facie* obvious to an ordinary artisan to apply Guyuron's preparation over a wound and around the outside edge of a wound in the range of 2-100 mm as is typical with other liquid bandages, ointments, and topical treatments known in the art.

Appellant argues that one would have been discouraged from using Guyuron's adhesives with Abber's devices (brief, p. 9).

Appellant's argument is based on the incorrect premise that Abber's devices are required to have liquid permeability (see brief at the top of p. 10). Notably, appellant provides no citation as to any teaching in Abber that supports the position that the devices must be liquid permeable. The examiner has been unable to locate such a teaching anywhere in Abber. Rather, Abber teaches that the *pressure sensitive adhesive* should have at least some degree of liquid permeability. As appellant is aware, Abber is not relied upon for a teaching of the pressure-sensitive adhesive, given that Guyuron teaches the exact silicone adhesive composition instantly claimed (see the par. bridging pgs. 14-15 of the Office Action dated 5/19/2009). Rather, based on Abber's teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use Guyuron's own composition as an adhesive for medical devices as taught by Abber, to provide a suitable adhesive for a medical device. As discussed above, Abber discloses crosslinked pressure sensitive adhesive silicones *substantially similar* to those of Guyuron, and teaches their use as adhesives for various medical devices (abstract; col. 1, line 11-16; claims 1-4). The use of Guyuron's compositions as adhesives for medical articles amounts to no more than combining known prior art elements (i.e. crosslinked silicone compositions) according to known methods (i.e. use of as these compositions as adhesives for medical devices) to yield predictable results (i.e. acceptable adhesion of the medical devices to the skin). The ordinary artisan would have had a high expectation of success in doing so since the prior art establishes that substantially identical compositions are useful for exactly the same purpose and since Guyuron suggests such a use. Further, even if, *in arguendo*,

the adhesives of Abber were at issue (which they are not), the adhesives of Guyuron are substantially similar and also possess a measure of permeability. While Guyuron teaches that the composition helps to retain moisture in the wound, this property depends upon the thickness of the composition applied (col. 10, lines 63-65). Thus, Guyuron suggests that some degree of liquid permeability is inherent to the composition, and that this characteristic can be adjusted by altering the thickness of the composition applied to the wound. Appellant has not even shown a patentable difference between the silicone adhesives taught by Guyuron and Abber, even if this were a relevant issue to the rejection.

Appellant argues claim 15 depends from claim 14, and that claim 14 was not included in the rejection over Guyuron and Abber (brief, p. 10).

Appellant's point in making this argument is unknown as claim 14 is clearly rejected over Guyuron. There is nothing inconsistent in adding a secondary reference to reject a dependent claim when the primary reference was used to reject the claim upon which the dependent claim depends.

Regarding claim 15, appellant argues that Guyuron fails to suggest applying the composition around a wound, per the arguments regarding claim 14, *supra* (brief, p. 10).

The arguments with respect to claim 14 are addressed *supra*, and that discussion is incorporated into the discussion of claim 15. As discussed *supra*, Guyuron is not deficient, and suggests application of the composition to a wound, which an artisan would understand must include the non-wounded skin around a wound. Further, appellant admits that the combination of Guyuron and Abber teaches applying

a medical device to a preparation over a wound (see the 2nd par. of p. 11 of the brief). It is reiterated that the instant claims in no way exclude the composition from the wounded tissue, and do not limit application of the composition to ONLY the non-wounded skin. Guyuron's method, applying the same composition to the wound *and* (implicitly) to the skin adjacent to the wound as well, renders the instantly claimed method obvious. It is the examiner's position that any artisan practicing Guyuron's method would surely apply the composition to the non-wounded skin around the wound within the wide width range 2-100 mm) instantly claimed. Furthermore, it is well within the skill of an ordinary artisan to determine the precise amount and pattern of application optimal for a particular wound depending on the shape and nature of the wound. Thus, it would be *prima facie* obvious to an ordinary artisan to apply Guyuron's preparation over a wound and around the outside edge of a wound in the range of 2-100 mm as is typical with other liquid bandages, ointments, and topical treatments known in the art.

Appellant argues claim 16 is drawn to liquid tight dressings and that the adhesives of Abber require some liquid permeability (brief, p. 11).

The above discussion is incorporated herein. Again, appellant is making an improper correlation between the requirements of Abber's adhesives and those of Abber's devices. However, at the bottom of p. 11, appellant correctly states that it is the *adhesives* of Abber which should have some amount of liquid permeability, not the devices themselves. The adhesives of Abber are not at issue. Rather, the issue is whether the teachings of Abber render obvious the use of crosslinked silicone adhesives with medical devices, which they do. All that is required of Abber to cure the

deficiency of Guyuron is the teaching that silicone-based adhesives can be used in combination with medical devices, which is clearly provided as discussed above. While Abber's *adhesives* must have at least some liquid permeability character to allow diffusion of drugs in transdermal patch preparations, there is nothing inconsistent with having a liquid permeable adhesive and an occlusive or liquid tight patch structure adhered to the skin by way of said adhesive. In fact, this configuration is conventional in the transdermal patch art. Occlusive outer layers are commonly used to direct the flow of the drug in one direction (into the skin), and protect the permeable adhesive drug layer from the influx of external water, abrasion, contamination, etc. Regarding claim 16, Abber teaches the use of the adhesive in conjunction with bandages such as transdermal therapeutic devices (abstract; col. 2, lines 63-68). Abber teaches the use of transdermal devices having semi-permeable layers with respect to the drug in the transdermal device (col. 1, lines 48-50; col. 4, lines 60-64) (note that semi-permeable to the drug is not equivalent to liquid permeable), and clearly states that the adhesives have general applicability to essentially any transdermal device which must be adhesively placed in contact with the skin (col. 5, lines 4-10). Further, Abber teaches that the transdermal devices occlude an area of the skin (Table III, under Swelling or Redness). The instant specification defines a liquid-tight dressing as merely having one layer that is liquid-tight (par. [0026]). Transdermal devices comprising at least one liquid-tight layer are well known in the art (i.e. occlusive patches as taught by Abber). An ordinary artisan would be motivated to use such a liquid-tight device in conjunction with the silicone adhesives taught by Guyuron because Guyuron teaches that the

compositions act as barriers to retain moisture in the wound (col. 10, lines 63-65; col. 11, lines 16-18). This supports the reasoning put forth by the examiner, and is acknowledged by appellant in the last full par. on p. 11 of the brief.

For at least the above reasons, it is apparent that the rejections are proper within the meaning of U.S.C. 103, and render the claimed invention obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Kevin S Orwig/

Examiner, Art Unit 1611

Conferees:

/David J Blanchard/
Primary Examiner, Art Unit 1643

/Jon D. Epperson/
Primary Examiner